ORIGINAL

IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO
CIVIL DIVISION

TERESA & BRAD NICHOLS,
969 St. Rt.28 Lot 77
Milford, OH 45150

Plaintiffs,

v.

ABUBAKAR ATIQ DURRANI, M.D.,
Serve: Orthopedic & Spine Institute
203 Canal Road
Lahore 54000 Pakistan
(Serve by regular mail

CENTER FOR ADVANCED SPINE TECHNOLOGIES, INC.
Serve: Orthopedic & Spine Institute
203 Canal Road
Lahore 54000 Pakistan
(Serve by regular mail

And

WEST CHESTER HOSPITAL, LLC
7700 UNIVERSITY DRIVE
WEST CHESTER, OH 45069
SERVE: GH&R BUSINESS SVCS., INC.
511 WALNUT STREET
1900 FIFTH THIRD CENTER
CINCINNATI, OH 45202
(Serve via Certified mail)

REGULAR MAIL WAIVER

And

UC HEALTH
SERVE: GH&R BUSINESS SVCS., INC.
511 WALNUT STREET
1900 FIFTH THIRD CENTER
CINCINNATI, OH 45202
(Serve via Certified mail)

REGULAR MAIL WAIVER

Case No. A 1601569

JUDGE

COMPLAINT
& JURY DEMAND

(ALL NEW DR. DURRANI CASES SHALL GO TO JUDGE RUEHLMAN PER HIS ORDER)

D113855614 INI

FILED
2016 MAR 16 P 1:35
TRACY WINKLER
CLERK OF COURTS
HAMILTON COUNTY, OH

EXHIBIT A

Defendants. :

Come now Plaintiffs, Teresa and Brad Nichols, and file this Complaint and jury demand, pursuant to the agreement of the parties and Order of the Court, and state as follows:

1. At all times relevant, Plaintiffs were residents of and domiciled in the State of Ohio.

2. At all times relevant, Defendant Dr. Abubakar Atiq Durrani (hereinafter "Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.

3. At all times relevant, Center for Advanced Spine Technologies, Inc. (hereinafter "CAST"), was licensed to and did in fact perform medical services in the State of Ohio, and was and is a corporation authorized to transact business in the State of Ohio and Kentucky.

4. At all times relevant, West Chester Hospital, LLC (hereinafter "West Chester Hospital"), was a limited liability company authorized to transact business and perform medical services in the State of Ohio and operate under the trade name West Chester Hospital.

5. At all times relevant, Defendant UC Health Inc., was a duly licensed corporation which owned, operated and/or managed multiple hospitals including, but not limited to West Chester Hospital, and which shared certain services, profits, and liabilities of hospitals including West Chester.

6. At all times relevant herein, West Chester Medical Center, Inc., aka West Chester Hospital held itself out to the public, and specifically to Plaintiffs, as a hospital providing

competent and qualified medical and nursing services, care and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.

7. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC.

8. UC Health Stored BMP-2 at UC Health Business Center warehouse located in Hamilton County.

9. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC. UC Health is located in Hamilton County making Hamilton County appropriate to bring this lawsuit.

10. The amount in controversy exceeds the jurisdictional threshold of this Court.

11. The subject matter of the Complaint arises out of medical treatment by Defendants in Butler County, Ohio. This Court is thus the proper venue to grant Plaintiff the relief sought.

12. This case has been previously dismissed pursuant to Civ. R. 41(A)(1)(a) and is now being refiled within the time allowed by O.R.C. 2305.19.

FACTUAL ALLEGATIONS OF PLAINTIFF

13. In 2010, Plaintiff sought medical help from Dr. Durrani at his office at CAST for chronic back pain associated with years of dancing.

14. Dr. Durrani advised that surgery was necessary to resolve Plaintiff's ongoing back pain.

15. Dr. Durrani diagnosed Plaintiff with kyphotic deformity of the thoracic spine, thoracic disk herniation, and thoracic spinal stenosis. Dr. Durrani informed Plaintiff that the only possible treatment was surgery.

16. Dr. Durrani promised that Plaintiff would experience immediate pain relief following her first surgery.

17. On December 17, 2010, Dr. Durrani performed surgery on Plaintiff at West Chester Hospital. The surgery involved (1) video-assisted thoracoscopic anterior discectomy from T5-T6 to T11-T12; (2) anterior interbody fusion from T5-T6 to T11-T12; (3) placement of anterior interbody cage from T5-T6 to T11-T12; (4) posterior spinal instrumentation from T3 to L2; and (5) posterior spinal fusion using auto and allograft from T3 to L2 ["the first surgery"].

18. After this surgery, Plaintiff's pain became worse than it had been prior to the surgery.

19. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this first surgery without Plaintiff's knowledge or consent, causing harm.

20. Plaintiff continued to have severe back pain, and tried multiple forms of physical therapy over the next several months at the advice of Dr. Durrani.

21. In June of 2012, Plaintiff returned to Dr. Durrani at his CAST office. Dr. Durrani then recommended a second surgery with a diagnosis of lumbar spinal stenosis, lumbar degenerative spondylolisthesis, and foraminal stenosis.

22. On June 13, 2012, Plaintiff underwent a second surgery by Dr. Durrani at West Chester Hospital. The surgery involved (1) direct lateral lumbar interbody discectomy from L3-L4; (2) direct lateral interbody discectomy from L4-L5; (3) direct lateral

interbody fusion using auto and allograft from L3-L4 and direct lumber interbody fusion from L4-L5; (4) placement of direct lateral interbody cage Medtronic pedicle from L3-L4; (5) placement of direct lateral interbody cage at L4-L5; (6) posterior spinal instrumentation of L3, L4, and L5; (7) posterior spinal fusion from L2-L3, L3-L4, and L4-L5 using auto and allograft; (8) extension of fusion from L2-L5; (9) lumbar laminectomy from L4-L5; and (10) lumbar foraminotomy from L4-L5, right side ["the second surgery"].

23. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this second surgery without Plaintiff's knowledge or consent, causing harm.

24. Following the second surgery, Plaintiff continued to experience pain in her back, hips, and legs which caused her to fall down stairs four times.

25. Dr. Durrani recommended a drain be inserted into Plaintiff to drain a pocket of fluid that developed on her spine. Dr. Durrani informed Plaintiff that the drain would alleviate her pain.

26. The drain did not alleviate Plaintiff's pain and she continued to suffer severe pain in her back, hips, and legs.

27. Plaintiff, to this day, continues to suffer from severe back pain, neck pain, hip pain, leg pain, headaches, and has missed large amounts of work due to pain and discomfort.

28. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

29. As a direct and proximate result of these surgeries and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

30. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

MORE SPECIFIC ALLEGATIONS BASED UPON DISCOVERY AND DEPOSITION TESTIMONY

31. This information is to demonstrate the overall negligence and inappropriate actions of Dr. Durrani and the hospitals he worked with and/or for and/or in an individual capacity.

32. Krissy Probst was Dr. Durrani's professional and personal assistant handling professional, academic, travel, surgery scheduling, his journals, his Boards, his credentialing, his personal affairs and his bills.

33. Krissy Probst worked as Dr. Durrani's assistant for three years at Children's Hospital from 2006, 2007, and 2008.

34. Krissy Probst reported Dr. Durrani to Sandy Singleton, the Business Director at Children's for his having an affair with Jamie Moor, his physician assistant.

35. Krissy Probst resigned in 2008 from Dr. Durrani and remained working for three other surgeons in the Orthopedic Department.

36. Krissy Probst worked in the Orthopedic Department for eleven years from 2002-2013. She retired in May, 2013.

37. Krissy Probst confirmed Dr. Durrani claims being a Prince, when he is not.

38. According to Krissy Probst, Dr. Crawford, an icon in pediatric orthopedics treated Dr. Durrani "like a son."

39. According to Krissy Probst, Dr. Crawford, Chief of Orthopedics at Children's unconditionally supported Dr. Durrani no matter the issues and problems Dr. Durrani faced.

40. Dr. Durrani's patient care at Children's Hospital dropped off considerably after Jamie Moor became his physician assistant and they began their affair.

41. Dr. Durrani was the only orthopedic spine surgeon at Children's who would perform a dangerous high volume of surgeries.

42. At Children's, Dr. Durrani would begin a surgery, leave and have fellows and residents complete a surgery or do the full surgery while he was in his office with Jamie Moor, his physician assistant for four or five hours.

43. Children's Board and administration knew about Dr. Durrani doing too many surgeries and not properly doing the surgeries. They did nothing.

44. Dr. Durrani argued to Children's administration when they complained to him that he made them money so Children's tolerated him and allowed him to do what he wanted.

45. Dr. Durrani, when told by Children's that Jamie Moor had to leave, told Children's that he would leave too.

46. Dr. Agabagi would do one spine patient a day at Children's because it takes normally eight hours for a full fusion.

47. Dr. Durrani would schedule two to three spine surgeries a day at Children's.

48. Dr. Durrani would repeatedly have the Business Director, Sandy Singleton, or OR Director allow him to add surgeries claiming they were emergencies when they were not.

49. Dr. Durrani would leave a spine surgery patient for four or five hours in the surgery suite under the care of fellows or residents, unsupervised and sit in his office and check on the surgery as he pleased.

50. Dr. Peter Stern did not like Dr. Durrani while Dr. Durrani was at Children's because he knew all about his patient safety risk issues. Yet, Dr. Stern supported, aided and abetted Dr. Durrani's arrival at West Chester. It defies comprehension, but was for one of the world's oldest motives—greed of money.

51. There is also a Dr. Peter Sturm, an orthopedic at Children's who also had no use for Dr. Durrani.

52. Dr. Durrani chose his own codes for Children's billing which he manipulated with the full knowledge of Children's Board and management.

53. Dr. Durrani was dating and living with Beth Garrett, a nursing school drop-out, with the full knowledge of his wife Shazia.

54. Dr. Durrani was close with David Rattigan until David Rattigan pursued Jamie Moor and Dr. Durrani would not allow David Rattigan in the OR at Children's for a long time.

55. Dr. Durrani, while claiming to have riches, does not. Dr. Durrani's wife's family paid for Dr. Durrani's education and it is her family with the significant wealth.

56. Medtronics paid for Dr. Durrani's trips and paid him $10,000 fees for speaking or simply showing up at a spine conference.

57. Krissy Probst's business director told her to save all Dr. Durrani related documents and information and she did.

58. While doing research at Children's, Dr. Durrani would misstate facts regarding his research. Children's knew he did this.

59. Dr. Durrani ended on such bad terms with Children's Hospital he was not allowed on the premises after his departure in December 2008, yet he performed a spine surgery there in February 2009.

60. Eric J. Wall, MD was the Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

61. Sandy Singleton, MBA was the Senior Business Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

62. On information and belief, Dr. Durrani used his relationships with Children's officials to purge his Children's file of all patient safety and legal issues which had occurred as part of his departure "deal" which Defendants hide with privilege.

INFUSE/BMP-2

I. BACKGROUND INFORMATION

63. The Deters Law Firm, P.S.C., represents approximately 500 Plaintiffs in medical malpractice actions against a former Northern Kentucky/Cincinnati-area spine surgeon named Abubakar Atiq Dr. Durrani (Dr. Durrani), his company, Center for Advanced Spine Technologies, Inc. (CAST), and several area hospitals including, but not limited to, West Chester Hospital (WCH), University of Cincinnati Health (UC Health), Cincinnati Children's Hospital Medical Center (CCHMC), Christ Hospital, Deaconess Hospital, Good Samaritan Hospital and Journey Lite of Cincinnati, LLC (Journey Lite) (collectively Hospitals).

64. Dr. Durrani performed unnecessary, fraudulent, dangerous, and ultimately damaging surgeries on these Plaintiffs while working for and with these Hospitals.

65. The scheme and artifice to defraud that Dr. Durrani devised, executed, and attempted to execute while working for and with the Hospitals included the following patterns and practices:

a. Dr. Durrani persuaded the patient that surgery was the only option, when in fact the patient did not need surgery.

b. Dr. Durrani told the patient that the medical situation was urgent and required immediate surgery. He also falsely told the patient that he/she was at risk of grave injuries without the surgery.

c. Dr. Durrani often told his cervical spine patients that they risked paralysis or that his/her head would fall off if he/she was involved in a car accident, ostensibly because there was almost nothing attaching the head to the patient's body.

d. Dr. Durrani often ordered imaging studies such as x-rays, CT scans, or MRIs for patients but either did not read or ignored the resulting radiology reports.

e. Dr. Durrani often provided his own exaggerated and dire reading of the patient's imaging study that was either inconsistent with or was plainly contradicted by the radiologist's report. At times, Dr. Durrani provided a false reading of the imaging.

f. Dr. Durrani often dictated that he had performed certain physical examinations and procedures on patients that he did not actually perform.

g. Dr. Durrani often ordered a pain injection for a level of the spine that was inconsistent with the pain stated by the patient or with that indicated by the

imaging. Dr. Durrani also scheduled patients for surgeries without learning of or waiting for the results of certain pain injections or related therapies.

h. Dr. Durrani often dictated his operative reports or other patient records months after the actual treatment had occurred.

i. Dr. Durrani's operative reports and treatment records contained false statements about the patient's diagnosis, the procedure performed, and the instrumentation used in the procedure.

j. When a patient experienced complications resulting from the surgery, Dr. Durrani at times failed to inform the patient of, or misrepresented the nature of, the complications.

k. All of the above-mentioned actions were done with the knowledge, cooperation, or intentional ignorance of the Hospitals because Dr. Durrani was one of the biggest moneymakers for the Hospitals.

66. In addition to the civil medical malpractice actions against Dr. Durrani, on August 7, 2013, he was indicted by the Federal Government for performing unnecessary surgeries and for defrauding the Medicare and Medicaid programs. Specifically, the ten-count complaint charged Dr. Durrani with health care fraud, in violation of 18 U.S.C. § 1347, and making false statements in health care matters, in violation of 18 U.S.C. § 1035. There was a subsequent superseding indictment adding over 30 counts.

67. Following these criminal indictments, in December of 2013 and prior to the first Plaintiff's trial in these actions, Dr. Durrani fled the United States and returned to Pakistan. He has not returned to the United States to face allegations of either criminal or civil liability.

68. Among Dr. Durrani's and the Hospitals' professional failings was the use of a synthetic bone-morphogenetic protein called BMP-2, which was marketed under the

trade name "Infuse." Dr. Durrani used BMP-2/Infuse in ways that were either not approved by the federal Food and Drug Administration (FDA) or that were specifically contraindicated as noted on the FDA-approved product labeling. The Defendants had full knowledge of this fact.

69. BMP-2/Infuse was, at the time of the surgeries in question, and currently still is manufactured by a company called Medtronic, Inc. (Medtronic).

70. Dr. Durrani predominantly used BMP-2/Infuse on patients at WCH, which is owned by UC Health.

71. It is Plaintiffs' position that this non-FDA-approved use of BMP-2/Infuse was not only negligent, and fraudulent, but criminal based upon the manner in which it was allowed to be used by Dr. Durrani at West Chester, all with the knowledge and full support of the Defendants.

II. THE PLAYERS REGARDING BMP-2

72. Dr. Durrani is a citizen of the Republic of Pakistan and was a permanent resident of the United States who, from approximately 2005 to 2013, worked as a spine surgeon in and around Cincinnati, Ohio, until he fled the United States to escape civil liability and criminal prosecution.

73. Medtronic is an Irish corporation, with its principal executive office located in Dublin, Ireland, and its operational headquarters located in Minneapolis, Minnesota. Medtronic is the world's third largest medical device company and manufactures and markets BMP-2/Infuse. Medtronic sales representatives were also present during the experimental surgeries performed on Plaintiffs, who are clients of the Deters Law Firm.

74. CAST was a corporation organized under the laws of Ohio and had business and medical offices in Florence, Kentucky and Evendale, Ohio. CAST was owned, in whole or in part, by Dr. Durrani.

75. Bahler Medical, Inc. is a manufacturer of medical implants and is a corporation located in the state of Ohio.

76. David Rattigan is an Ohio resident and was and is a sales representative for Medtronic. Further, he is affiliated with Bahler Medical, Inc., was involved in many of the transactions involving BMP-2, and was present for the experimental surgeries in which BMP-2 was used.

77. West Chester Hospital, LLC is a corporation organized under the laws of Ohio. It provides medical facilities and billing support to physicians, including Dr. Durrani, in the state of Ohio. WCH is owned by UC Health.

78. UC Health is a private, non-profit corporation organized under the laws of Ohio. It provides medical facilities, management, administrative, ancillary, and billing support to physicians, and it owns WCH.

79. CCHMC is a medical facility in Ohio where Dr. Durrani was an employee until approximately 2008.

III. WHAT IS BMP-2/INFUSE?

80. The full name of BMP-2 is "Recombinant Human Morphogenetic Protein-2" (also called rhBMP-2). The following definitions apply:

a. Recombinant – Artificially created in a lab;

b. Morphogenetic – Evolutionary development of an organism;

c. Protein – Essential for growth and repair of tissue.

81. Recombinant human protein (rhBMP-2) is currently available for orthopedic usage in the United States.

82. Medtronic manufactured, marketed, sold, and distributed BMP-2 under the trade name "Infuse."

83. BMP-2 has been shown to stimulate the production of bone.

84. Implantation of BMP-2 in a collagen sponge induces new bone formation and can be used for the treatment of bony defects, delayed union, and non-union.

BMP-2 AS A BIOLOGIC

85. BMP-2 is not a device, but instead it is a biologic. *See* July 2009 American Medical Association Article and 2011 Stanford School of Medicine Article.

86. According to the FDA, "[a] 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service ActSec.351(i)1."Available http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

87. BMP-2 is a Bone-Morphogenetic Protein that is used to promote bone creation and remolding and falls under the definition of a biologic. *See* AMA article ("bone forming properties") and Stanford Article. BMP-2 differs from a medical device in that once implanted, it can only be removed days after surgery. If a patient had a complication due to BMP-2 and did not discover this complication until year after surgery, the patient could not have BMP-2 removed to reduce the complication because BMP-2 is so integrated into the patient's bone.

88. A patient has a right to determine what happens to his or her body and the preservation of that right requires that the patient be informed when a bone growth product, that causes irreversible harm, is placed in his or her body.

WHEN IS IT USED?

89. Recombinant human BMPs are used in orthopedic applications such as spinal fusions, non-unions, and oral surgery.

90. The bone graft contains two parts. The first is a solution of human bone growth protein or morphogenetic protein-2. This protein is found in the human body in small dosages and is important for the healing and formation of bones. The protein is genetically engineered to be utilized in the Infuse Bone Graft product, and it is employed for the stimulation of formation and growth in bones.

91. The second part of the bone graft is an absorbable collagen sponge.

92. Both components of the Infuse Bone Graft structure are used to fill the LT-Cage Lumbar Tapered Fusion Device. This chamber is intended to restore the deteriorated disc space to its original height.

93. FDA-approved use for the Infuse Bone Graft product is only for lower back surgery using an anterior lumbar interbody fusion (ALIF), a technique where the operation on the spine is conducted through the abdomen.

94. In addition, the Infuse Bone Graft product must be used in conjunction with Medtronic's LT-Cage. Use of BMP-2 without the LT-Cage is considered an "off-label" use.

CONTRAINDICATIONS OF USE

95. The FDA specifically warns against the use of Infuse in the cervical spine, citing reports of "life-threatening complications."

96. Any use of Infuse other than in lumbar spine surgeries with the LT-Cage is considered "off-label" use

97. Infuse should never be used on the skeletally immature patient, i.e., in patients less than 18 years of age or those with no radiographic evidence of epiphyseal closure.

98. Infuse should never be used in the vicinity of a resected or extant tumor.

99. Infuse should never be used in those patients known to have active infection at the surgical site.

RISKS ASSOCIATED WITH OFF-LABEL USE

100. When used in an off-label manner, patients may experience problems with pregnancy, including but not limited to: complications in fetal development; allergic reactions to titanium, bovine type I collagen, or bone morphogenetic protein–2; infection; the creation or intensification of tumors; liver or kidney disease; lupus or human immunodeficiency virus (HIV/AIDS); problems with radiation, chemotherapy, or steroids if a patient is malignant; paralysis; bowel and/or bladder dysfunctions; sexual disorders, including sterilization and incompetence; respiratory failure; excessive bleeding, and; death.

IV. THE REGULATORY PROCESS

101. The Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., established two separate approval processes for medical devices: Pre–Market Approval (PMA) and Pre–Market Notification.[1]

[1] *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

102. The FDA's PMA process is lengthy and involves extensive investigation by the FDA. The PMA application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before FDA approval can be obtained under this process. FDA regulations also require PMA applicants to submit copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(10). The FDA approves a PMA application only after extensive review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.[2]

103. In contrast, the FDA's Pre–Market Notification process is more abbreviated and involves less FDA oversight. This process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. Pre–Market Notification applicants must also submit their proposed labeling. 21 C.F.R. § 807.87. If the FDA determines that a device is substantially equivalent to a device that was on the market prior to the enactment of the MDA in 1976, the applicant is free to market the device.

104. BMP-2 received PMA (PMA number P000058) for the Infuse/BMP-2 Lumbar Tapered Fusion Device, which PMA provided for limited use with specific requirements for its use on individuals. See Medtronic Package Insert.

SCOPE OF THE PMA AND PRODUCT LABELING

105. The PMA for BMP-2 provided that the product may only be used in patients with the following characteristics:

d. Skeletally mature patient, AND

[2] *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

e. At levels L2-S1, AND

f. Confirmed degenerative disc disease (DDD), AND

g. Using only an open anterior or anterior laparoscopic approach, AND[3]

h. Six months of non-operative treatment prior to treatment with the device, AND

i. In combination with the metallic LT-CAGE.[4]

See Medtronic Package Insert, "INDICATIONS."

106. According to Medtronic's package insert for BMP-2/Infuse as well as other industry literature, the following risks are associated with the use of BMP-2/Infuse:

A. Male Sterility

B. Cancer

C. Increased progression of cancer

D. Suffocation of the cervical region

E. Bone fracture

F. Bowel/bladder problems

G. Loss of spinal mobility or function

H. Change in mental status

I. Damage to blood vessels and cardiovascular system compromise

J. Excessive bone mass blocking the ability to treat pain

K. Damage to internal organs and connective tissue

L. Death

M. Respiratory problems

N. Disassembly and migration of components

[3] The anterior interbody fusion approach was developed because the risk of non-union (pseudarthrosis) is significantly higher in posterior approaches. The biggest risk factor for fusion surgery is non-union.

[4] Instrumented fusions involve hardware and are more stable fusions with a shorter recovery time than non-instrumented fusions.

O. Dural tears

P. Ectopic and exuberant bone formation

Q. Fetal development complications (birth defects)

R. Foreign body (allergic) reaction

S. Gastrointestinal complications

T. Incisional complications

U. Infection

V. Insufflation complications

W. Neurological system compromise

X. Non-union

Y. Delayed union

Z. Mal-union

AA. Change in curvature of spine

BB. Retrograde ejaculation

CC. Scars

DD. Tissue and nerve damage

EE. Itching

FF. Pain

GG. Hematoma

HH. Anaphylactic reaction

II. Elevated erythrocyte sedimentation rate

107. Injury Percentages:

j. Ectopic Bone Growth-63%

k. Inflammatory Neuritis-15%

l. Osteolysis/Subsidence-13%

m. Acute Swelling-7%

n. Retrograde Ejaculation-2%

o. 85% of time, BMP-2 implanted in off-label use

108. Not a single one of these risks in the last two paragraphs were ever explained to a single patient at Children's Hospital by Dr. Durrani.

109. BMP-2 was NOT approved by the FDA for use in the cervical and thoracic spine and BMP-2 was NOT safe or approved for use in children less than 21 years of age. These uses are considered "off-label."

"OFF-LABEL" USE

110. A use of a device is considered "off-label" if it is not approved under the Pre-Market Approval process OR cleared for such use pursuant to 21 U.S.C. § 360c(f) (also known as "the 510k premarket notification process").

111. Infuse can be implanted in an off-label manner in three ways:

p. Approach/position: Any approach other than an anterior approach;

q. Product: Failure to use LT-Cage (or any cage); mixing rhBMP-2 with other grafting products like Allograft or Autograft;

r. Discs: Use on multiple levels or on a level outside of L2-S1.

112. Dr. Durrani and the Hospitals in which he performed surgeries repeatedly used BMP-2 in these non-FDA-approved manners.

THE NON-COMPLIANCE WITH THE REGULATORY PROCESS

113. The PMA 000058 "Conditions of Approval" specifies the following condition: "Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by the FDA ... [a] PMA supplement or alternate submission shall comply with applicable requirements under 21 C.F.R. 814.39[.]"

114. 21 C.F.R. 814.39 requires a PMA supplement pursuant to subsection (a)(1) for new indications of use of the device and pursuant to subsection (a)(6) for changes in components.

115. The PMA 000058 "Conditions of Approval" notes the post-marketing reporting requirement imposed by 21 C.F.R. 814.84, particularly "Identification of changes described in 21 C.F.R. 814.39(a)." Medtronic did not comply with this requirement relating to the intended uses and componentry.

116. The FDA can impose post-approval requirements in the PMA pursuant to 21 C.F.R. 814.82, and this fact results in the device being characterized as "restricted" pursuant to 21 U.S.C. § 360j(e) for purposes of 21 U.S.C. § 352(q). Section 352(q) states that any restricted device that is distributed or offered for sale with false or misleading advertising is "misbranded."

117. "Indications for use" is a necessary part of the PMA application and the "Indications for use" are required to be limited by the application. Any different use is inconsistent with the PMA.

118. A device that fails to meet the requirements of the PMA or 21 C.F.R. 814 is "adulterated" as defined by 21 U.S.C. § 351(f).

119. 21 C.F.R. 801.6 defines a misleading statement related to a DIFFERENT device contained in the label delivered with the device intended to be used will render the device to be used misbranded.

120. Medtronic did not apply for a PMA supplement, as required by the FDA generally and PMA 000058 specifically, for the off-label uses, nor did it provide warnings of the

risks known about the off-label uses. All named Defendants in these cases knew about the occurrences of off-label use.

121. The PMA requires an application prior to marketing for new indicated uses by incorporating the federal requirements and explicitly reciting the text of 21 C.F.R. 814.39 and 814.84 and by specifically stating the range of indicated uses on the PMA.

V. MEDTRONIC

122. In or about 2001, Medtronic began preparing for the launch of two spinal fusion products, PYRAMID and INFUSE (BMP-2), which it projected would enjoy broad application with spinal surgeons and their patients on a nationwide basis.

123. Medtronic anticipated that both products would initially be limited in application.

124. Motivated by greed and a desire to gain competitive advantage in the marketplace, Medtronic began a course of conduct designed to broaden the application of both products by end-users. The course of conduct involved fraud, false statements, material misrepresentation, and deceit for the purpose of broadening the sales of these products beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

125. On or after July 2, 2002, Medtronic received notification that its Pre-Market Approval application for its BMP-2/Infuse bone graft products had been approved by the FDA. However, such approval was limited to the application of the device from the L4 through S1 levels. Further, the approval mandated the conduct of post-approval studies to evaluate the long-term performance of the BMP-2 bone graft and to study the potential side effects and complications such as the promotion of tumors by the bone

morphogenetic protein component of BMP-2. Other studies were conducted as well. See "Allegations against Medtronic in the Unsealed Mississippi False Claims Case."

126. Medtronic engaged in a fraudulent course of conduct designed to maximize its revenues from BMP-2, regardless of whether it would eventually be allowed to remain on the market.

127. One of the physicians Medtronic co-opted into its fraudulent scheme was a Thomas A. Zdeblick, M.D. Dr. Zdeblick was an orthopedic surgeon whose invention, the LT-Cage, was the only approved device to act as the delivery vehicle for BMP-2 into the body.

128. Dr. Zdeblick enjoyed a position within the scientific community as a Key Opinion Leader, and he was both a practicing orthopedic surgeon and professor at the University of Wisconsin.

129. In one of Dr. Zdeblick's first attempts to tout his LT-Cage and rhBMP-2, which would become the active ingredient in the ultimate Infuse/BMP-2 product, he encountered some drawbacks to his goal of promoting his and Medtronic's products, which arose from the policy of certain industry journals, including the journal *Spine,* which followed industry standards before printing peer-reviewed material. See article in the journal *Spine,* published in 2000.

130. Not only were the drawbacks related to industry publishing standards, but the National Consumer Health Information and Health Promotion Act of 1976 enacted certain provisions at 42 U.S.C. § 300u, et seq., whereby the Federal Government had entered the field of medical research publication. Such standards promulgated by the Secretary of the predecessor to the U.S. Department of Health and Human Services

required that applications for grants and contracts must be subject to "appropriate peer review." See 42 U.S.C. § 300u-1.

131. The drawbacks encountered with the peer-reviewed *Spine* article were as follows:

a. Attribution that the study was "sponsored by Medtronic Sofamor Danek, Inc.;"

b. The study was conducted under FDA regulations, and was "...designed as a prospective, multicenter, nonblinded, randomized, and controlled pilot study;" and

c. It was accompanied by a cautionary comment, or Point of View, which minimized the exuberance and import of the article.

132. In the article, BMP-2 was touted by Zdeblick and the co-authors as the potential realization of a dream of Dr. Marshall Urist, a revered pioneer in the industry and discoverer of BMP, where it closed with the following: "...it is encouraging to note that Marshall Urist's seminal observation made more than 34 years ago may finally come to clinical fruition."

133. In the Point of View, a Dr. John O'Brien of London questioned whether there could be long-term problems associated with the product. He treated Zdeblick's study with caution and pointed out that simple plaster of Paris has achieved the same or similar results more than 50 years prior. He posited that, "[p]erhaps vascularization...fixation procedures are as important as the biochemical composition of the 'filler.'"

134. Vascularization is achieved through removal of the disc material between two vertebral bodies and then the scraping of the surfaces of the vertebral bodies in a fusion procedure; fixation is the process of securing the motion segment through medical hardware. In other, if the alternative proposed by Dr. O'Brien proved to achieve

equivalent or better results, Zdeblick and Medtronic's Infuse/BMP-2 products would be useless and unnecessary.

135. Certain efforts would follow in an attempt to alleviate the drawbacks encountered with the 2000 *Spine* journal article.

136. In 2002, Dr. Zdeblick was installed as the sole editor-in-chief of a medical journal known prior to his installation as the *Journal of Spinal Disorders*. Prior to his installation, the journal enjoyed a fourteen-year history under the co-editorship of Dr. Dan Spangler and Dr. Tom Ducker. Once installed, Dr. Zdeblick successfully supplanted Drs. Dan Spengler and Tom Ducker and became the sole editor-in-chief, a position which would enable him to have greater control and would aid his participation in the fraudulent scheme.

137. During this same time period, Dr. Zdeblick also enjoyed a position on the associate editorial board of the medical journal *Spine*, the leading publication covering all disciplines relating to the spine.

138. In one of Dr. Zdeblick's actions as editor-in-chief, he set about re-purposing the journal in a way that would aid him in the furtherance of the fraudulent scheme through the streamlining of the publication process.

139. In furtherance of the fraudulent scheme, Dr. Zdeblick re-purposed the journal and renamed it the *Journal of Spinal Disorders and Techniques* (JSDT), announcing that the new journal was "entering a new partnership with *Spine*." As part of this partnership, *Spine* would "continue to function as a broad-based scientific journal" tailored to both clinicians and scientists. However, the *Journal of Spinal Disorders and Techniques* would be directed solely to physicians in clinical practice.

140. Dr. Zdeblick's stated goal was "to provide a forum for up-to-date techniques…", and in furtherance of that goal, Dr. Zdeblick announced that his journal would publish Class II or better clinical articles but would "occasionally accept cutting edge articles with less than one-year follow-up." To justify this streamlined process, Dr. Zdeblick claimed as his goal the ability of his journal "to keep up with the fast pace of progress in the treatment of spinal patients."

141. Arm-in-arm with Medtronic and others, Dr. Zdeblick would in short order abuse his position of trust as the editor-in-chief of JSDT.

142. In the October 2002 edition, JSDT published an article entitled, "Anterior Lumbar Interbody Fusion using rhBMP-2 with Tapered Interbody Cages." This article was co-authored by, among others, Curtis A. Dickman, M.D., who was a developer of Medtronic's PYRAMID plate and who has been paid significant sums by Medtronic through royalty agreements, consulting agreements, and education training and speaking agreements.

143. In addition to his interest in the PYRAMID plate, Dr. Dickman had assisted Medtronic in the approval process for Infuse/BMP-2. As part of the pre-approval hearing process, Dr. Dickman and his Barrow Neurological Associates Group of Phoenix, Arizona had submitted a letter to the meeting of the FDA's Orthopedics and Rehabilitation Devices Advisory Panel, which met on January 10, 2002. In that letter, Dr. Dickman represented that "approval of BMP would provide a significant advance for patient outcome and satisfaction following spinal fusion."

144. In the October 2002 issue of JSDT touting the benefits of Infuse/BMP-2, Zdeblick and others failed to disclose their financial ties to Medtronic, though industry standards

require such acknowledgement. Not only did Dr. Zdeblick fail to disclose that he profited from each and every surgery which Infuse/BMP-2 was used through rights in the exclusive delivery vehicle, his LT-Cage, but no reference whatsoever to their financial ties to Medtronic was made either by Dr. Zdeblick or Dr. Dickman.

145. For years, the recognized gold standard for spinal bone grafts has been the use of autogenous bone, or bone harvested from the patient's own iliac crest, or hip bone. Medtronic designed to have its Infuse/BMP-2 product supplant autogenous bone as the gold standard in the medical community, and utilized false statements, a fraudulent enterprise and the support of Federal funds to do so.

146. As part and parcel of Medtronic's fraudulent scheme, the October 2002 study was published in Dr. Zdeblick's journal three months after Medtronic received FDA approval for Infuse. As the article shows, it was actually received on March 28, 2002 or after Dr. Zdeblick had accomplished installment as the editor-in-chief, and was accepted by Dr. Zdeblick's journal for publication on July 30, 2002.

147. At the same time Dr. Zdeblick's journal was publishing the initial article on Infuse, Dr. Zdeblick was already finalizing and preparing for subsequent publication a follow-up article to tout Infuse potentially as the new gold standard. A second article, co-authored by Dr. Zdeblick and two other co-authors of the original article, was entitled "Is Infuse Bone Graft Superior to Autograft Bone? An Integrated Analysis of Clinical Trials using the LT-Cage Lumbar Tapered Fusion Device."

148. This second article was published in Vol. 2 of 2003 and once again, there was no mention of Dr. Zdeblick's financial ties to Medtronic.

149. This second article would serve as the second covert advertisement for the Infuse product, and the article states that "the purpose of our analysis was to investigate the potential statistical superiority of Infuse bone graft to autograft…"

150. This second article went on to announce the July 2002 FDA approval of rhBMP-2.

151. This article included as an "acknowledgment" an expression of gratitude to the physicians "who provided patients for this study and to the clinic research group at Medtronic Sofamor Danek for their help in data collection and statistical analyses." However, the article still failed to advise the medical community that some or all of the authors reaching these conclusions touted as monumental had direct financial interests tied to those conclusions.

152. Rather, the failure to report these clear conflicts of interest on the part of those holding positions of trust both within the medical community and over patients was part of Medtronic's fraudulent enterprise. However, unchecked by appropriate peer review, Medtronic was able to systematically accomplish their goals.

153. In its 2003 Annual Report, and without recognizing that Zdeblick was being paid by Medtronic, Medtronic cited to Zdeblick's 2003 as reporting that Infuse "…may become the new gold standard in spinal fusion surgery."

154. By its 2006 Annual Report, if not earlier, Medtronic had removed all doubt, declaring that after its introduction in 2002, "Infuse Bone Graft quickly became the gold standard for certain types of lumbar fusion."

155. Medtronic's fraudulent scheme was successful and resulted in a revenue stream ranging from 700 to 900 million dollars per year.

156. It has been reported that around the same time these stories about Infuse were published, editors at the Spine Journal began receiving complaints from doctors around the country who were pointing out contradictions between papers published by doctors with financial ties to Medtronic and other data involving Infuse complications.' See *Journal Sentinel* article of John Fauber.

157. Through the use of these sham consulting, royalty and education/training agreements with its physician agents in this fraudulent enterprise, Medtronic has reaped windfalls in the billions of dollars. Medtronic has used this fraudulent enterprise and civil conspiracy to drive its vast profits and enhance its market position beyond that which it would have realized without engaging willfully, knowingly and potentially deliberate, conscious, or reckless indifference in the fraudulent enterprise and fraudulent concealment. See Mississippi case.

158. Defendants had full knowledge of all these facts pertaining to Medtronics.

VI. FDA PUBLIC HEALTH NOTIFICATION

159. On July 1, 2008 the FDA issued a Public Health Notification entitled "Life-Threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion."

160. This notification was sent to health care practitioners all across the United States warning of the complications associated with BMP-2, specifically when used in the cervical spine.

161. In the notification the FDA stated they received at least 38 reports of complications during the prior four years with the use of BMP-2 in cervical spine fusions.

162. The complications were associated with swelling of the neck and throat areas, which resulted in compression of the airway and/or neurological structures in the neck.

163. Some reports describe difficulty swallowing, breathing or speaking and severe dysphagia following cervical spine fusion using BMP-2 products had also been reported.

164. The notification further stated that, "since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

165. The Notification further emphasized the importance of fully informing patients of these potential risks and said that patients treated with BMP-2 in the cervical spine should know:

s. The signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area

t. That they need to seek medical attention immediately at the first sign of an airway complication

u. That they need to be especially watchful 2-14 days after the procedure when airway complications are more likely to occur

v. rhBMP-2 (contained in Infuse Bone Graft) has received pre-market approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease at one level from L2-S1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury.

166. Additionally, BMP is not approved in any manner for use in patients who are skeletally immature (<18 years of age) or pregnant.

167. Dr. Durrani and the Hospitals ignored ALL of these warnings and used BMP-2 in cervical spine surgeries, children, and those with known compromising factors such as osteoporosis, smoking, and diabetes.

168. Furthermore, the Notification stated that the FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

169. The Hospitals that allowed Dr. Durrani to use BMP-2 in their facilities failed to report any complications resulting from his use of BMP-2.

VII. SENATE FINANCE COMMITTEE REPORT

170. Medtronic's actions did not go unnoticed, and in June of 2011 the Senate Finance Committee began an investigation into the fraudulent actions of Medtronic.

171. Medtronic produced more than 5,000 documents pertaining to 13 different studies of BMP-2 for the investigation.

172. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into Medtronic, which revealed questionable ties between the medical technology company and the physician consultants tasked with testing and reviewing Medtronic products.

173. The investigation revealed that Medtronic employees collaborated with physician authors to edit and write segments of published studies on BMP-2/Infuse without publicly disclosing this collaboration.

174. These fraudulently-produced studies may have inaccurately represented BMP-2's risks and may have placed added weight on the side effects of alternative treatments.

175. The Senate investigation further found that Medtronic also maintained significant, previously undisclosed financial ties with physicians who authored studies about BMP-2, making $210 million in payments to physicians over a 15-year period.

176. Senator Baucus stated, "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. Patients everywhere will be better served by a more open, honest system without this kind of collusion."

177. Senator Grassley stated, "The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and the studies they feature. These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

178. Major findings of the investigation include:

a. Medtronic was involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's role in authoring or substantially editing these articles was not disclosed in the published articles. Medical journals should ensure that any industry role in drafting articles or contributions to authors is fully disclosed.

b. Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with BMP-2/Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

d. Medtronic officials inserted language into studies that promoted BMP-2 as a better technique than an alternative by emphasizing the pain associated with the alternative.

e. Documents indicate that Medtronic prepared one expert's remarks to the FDA advisory panel meeting prior to BMP-2 being approved. At the time, the expert was a private physician but was later hired to be a vice president at Medtronic in 2007.

f. Medtronic documents show the company successfully attempted to adopt weaker safety rules for a clinical trial studying BMP-2 in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

VIII. YODA STUDY

179. In response to the various controversies surrounding BMP-2/Infuse, including a June 2011 article in the journal *Spine,* the Yale University Open Data Access (YODA) team reached an agreement for Medtronic to provide full individual participant data from all their trials of rhBMP-2 and allow unrestricted independent re-analysis of this data.

180. The YODA study involved research teams at two universities – the University of York and the Oregon Health and Science University.

181. The review focused exclusively on the use of rhBMP-2 in patients undergoing spinal fusion surgery for treatment of degenerative disc disease, spondylolisthesis, or any other relevant spinal condition.

182. The three main objectives of the study were: 1) to examine the potential benefits of BMP-2, 2) to examine the potential harms of BMP-2, and 3) to assess the reliability of the published evidence base.

183. Medtronic submitted data from 17 studies, including 12 randomized controlled trials (RCTs).

184. In total, the YODA study analyzed the data from 1,409 participants.

185. Though the results showed moderate success with fusions as a result of BMP-2, the study found that BMP-2 results in several different complications including: arthritis, implant-related events, retrograde ejaculation, wound complications, and neurological, urogenital, and vascular events.

186. In regard to the alleged tampering with the peer-reviewed studies by Medtronic, the YODA study found that only two out of twenty peer-reviewed journal publications reported a comprehensive list of all adverse events that occurred during the studies.

187. Furthermore, the way in which adverse event data was presented in the literature was inconsistent, and the rationale for presenting some adverse events but not others was rarely clear.

188. The study concluded that for the period up to 24 months after surgery, treatment with BMP-2 increases the probability of successful fusion (according to Medtronic definitions and reports, which the study noted "were subjective so it is not possible to confirm whether reported successful fusions truly were successful" see YODA Study, p.

35) but this does not translate to clinically meaningful benefits in pain reduction, function, or quality of life. The small benefits in these outcomes observed from six months onward come at the expense of more pain in the immediate post-operative period and a possible increased risk of cancer.

189. Even more relevant to the case against Dr. Durrani and the Hospitals is the YODA study's conclusion that, "[i]t is very important that these findings are expressed clearly and discussed with patients so that they can make informed choices about the type of surgery they would prefer." *Id.*

190. The University of Oregon Study determined that Infuse/BMP-2 is not better than Autograft, while the University of York study determined that Infuse/BMP-2 offers only a slight and not statistically significant advantage over Autograft.

191. The YODA study concluded that Medtronic "misrepresented the effectiveness and harms through selective reporting, duplicate publication, and underreporting."

192. Adverse event categories such as heterotopic bone formation, osteolysis, and radiculitis were not included in participant databases or internal reports; therefore, the safety profile was not fully assessed.

193. The YODA study further concluded that Medtronic was involved in drafting, editing, and shaping the content of medical journal articles on Infuse/BMP-2 authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles.

194. Medtronic paid a total of approximately $210 million to the physician authors of Medtronic-sponsored studies on Infuse from November 1996 through 2010 for consulting, royalty and other arrangements.

195. An email exchange showed that a Medtronic employee recommended against publishing a complete list of adverse events or side effects possibly associated with Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

196. Medtronic officials inserted language into studies that promoted Infuse as a better technique than an alternative procedure by overemphasizing the pain associated with the alternative procedure.

197. Medtronic's actions violated the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. See United States Senate Committee on Finance, October 2012.

198. Infuse was intended for a single level anterior lumbar interbody fusion performed with all three components in a specific spinal region. The three components are a tapered metallic spinal fusion cage (NOT PLASTIC), a recombinant human (BMP) bone Morphogenetic Protein, and a carrier/scaffold for the BMP and resulting bone. The Infuse product is inserted into the LT-CAGE Lumbar tapered Fusion Device component to form the complete Infuse Bone Graft/LT–Cage Lumbar Tapered Fusion Device. These components must be used as a system. The Infuse Bone Graft component must not be uses without the LT-Cage Lumbar Tapered Fusion Device component.

199. BMP-2 is not supposed to be used in minors.

200. BMP-2 is not supposed to be used with smokers and diabetics because of vascular slowing.

201. BMP-2 should not be used with women in child bearing years.

202. BMP-2 is contraindicated for patients with a known hypersensitivity to rhBMP-2 and should not be used in the vicinity of a resected or extant tumor, in patients with active malignancy, or in patients undergoing treatment for a malignancy.

IX. DR. DURRANI AND BMP-2

203. Despite all of these warning signs, Dr. Durrani, with the full knowledge of the Defendants, continued to use BMP-2 in ways not approved by the FDA, or in an "off-label" manner.

204. As early as 2007, Dr. Durrani and UC Health knew there were issues with BMP-2 because insurance companies such as Anthem were refusing to pay for BMP-2.

205. Medtronic provided in writing to Dr. Durrani and CAST the approved uses for Infuse/BMP-2.

206. However, Dr. Durrani and the Defendants continued to use BMP-2 in off-label ways, including but not limited to:

a. Using BMP-2/Infuse in children, despite Medtronic specifically requiring it be used only in "skeletally mature patients;"

b. Using it outside the L2-S1 level of the spine;

c. Ignoring the requirement that BMP-2/Infuse only be used for Grade 1 spondylolisthesis or Grade 1 retrolisthesis;

d. Not requiring at least six months of non-operative treatment prior to the use of BMP-2/Infuse;

e. Using BMP-2/Infuse without the required cage;

f. Not using the "carrier scaffold" in conjunction with BMP-2/Infuse as required;

g. Using BMP-2/Infuse without proper training despite Medtronic's warning, "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience."

207. Dr. Durrani was a paid consultant for Medtronic.

208. According to Dr. Durrani's own deposition testimony in several cases, Medtronic required one of their representatives to be present in the operating room when its product BMP-2/Infuse is used.

209. Because Medtronic representatives were present in these surgeries, Medtronic knew when Dr. Durrani used BMP-2/Infuse outside the approved uses according to Medtronic's own guidelines.

210. Dr. Durrani was encouraged by Medtronic to obtain peer review and published studies from Medtronic sales representatives to support his use of BMP-2/Infuse.

211. Dr. Durrani was encouraged by Medtronic to be an advocate for his patients and describe how BMP-2/Infuse technology can benefit them.

212. When asked how he got his Medtronic grant, Dr. Durrani responded, "You apply to the Medtronic's corporate and say this is what we want to do, like everybody else in the country applies, and then they come and evaluate the thing and say, "Okay, we think it's worthy. We'll give you the grant."

213. In regard to his role as a Medtronic consultant, Dr. Durrani stated, "If there are certain products that they help us in developing, then they will come to us for a certain consultant role for a certain product development."

214. Dr. Durrani also stated, "I was involved in the development of the minimally invasive spine instrumentation."

215. Dr. Durrani gave conflicting reports on his financial relationship with Medtronic.

216. In a deposition, when asked when his relationship with Medtronic began, Dr. Durrani responded "2000-it's 2003, '04. Something in that category. I'm not sure. It's on the Medtronic website. You can go look at it."

217. Medtronic's website has no information regarding their relationship with Dr. Durrani.

218. In another deposition, Dr. Durrani stated he began his relationship with Medtronic in "2005 or '06."

219. Dr. Durrani also gave conflicting reports on how much compensation he received from Medtronic for his consultation services.

220. In one deposition, Dr. Durrani stated in response to an inquiry as to how much payment he received, "It's a standard compensation. Again, it's on the website, how much they've paid us."

221. Again, this information is not available on the Medtronic website.

222. In another deposition, when asked if he received income from Medtronic, Dr. Durrani replied, "No, I don't."

223. When questioned further if he received a fee as a consultant, he stated, "If you do a work, there is a contractual obligation that they have to pay you. As I told you in my last deposition, they did declare it on their website, so you can actually go on the website and see how much they paid."

224. In another deposition, Dr. Durrani stated that he received, "less than $10,000 in ten years" from Medtronic.

225. An email dated July 30, 2008 from Medtronic Senior Product Manager Katie Stamps to Dr. Durrani states that she "is in the process of working on the renewal of your [Dr. Durrani's] consulting agreement." As stated, this information is not available on Medtronic's website, nor is any information relating to Dr. Durrani's role as a consultant for Medtronic.

226. A CCHMC packet relating to its Orthopedics department indicated that Dr. Durrani received $60,000 in grants, contracts, or industry agreements from Medtronic Sofamor Danek in FY 2008.

227. Financial information discovered concerning Dr. Durrani's relationship with Medtronic was found in Dr. Durrani's biography on the website for the Orthopaedic & Spine Institute, which Dr. Durrani currently operates in Pakistan. The biography states that "Dr. Atiq Dr. Durrani has also received the Clinical Spine Fellowship Grant by the Department of Orthopaedic Surgery which was funded by Medtronic Sofamor Danek with a budget of $59,170 per year." See http://www.osi.com.pk/doctor/dr-atiq-Dr. Durrani-md/.

228. When a request was made to Medtronic regarding its affiliation with Dr. Durrani, the Medtronic Supplier Relations Team stated that Dr. Durrani's "name [is] not listed in our system."

229. Medtronic further responded to the Deters Law Firm's request that the firm would need a "Vendor I.D. Number," which neither Medtronic nor any other party has provided.

230. David Rattigan, was Dr. Durrani's main Medtronic representative from Bahler Medical.

231. David Rattigan and Medtronic have the same lawyer. Despite the Deters Law Firm's willingness to cooperate in scheduling the date for a deposition, they have refused until recently. Mr. Rattigan's deposition was taken June 5, 2015.

232. In summary, clients of the Deters Law Firm, with the full knowledge and intentional consent of all Defendants, became unsuspecting experiments for real world testing of Medtronic hardware and BMP-2, by and through Dr. Durrani and CAST, who had secret financial connections to Medtronic, improper motives, and submitted false claims. The government paid for many of these improper and unregulated experiments as a result of the false claims made by Dr. Durrani, with the knowledge of Medtronic, under the veil of "medically necessary" surgeries.

233. Despite repeated requests, Medtronic has refused to cooperate in providing any requested information and is actively downplaying their connections to Dr. Durrani.

X. THE DEFENDANTS AND BMP-2

234. The purpose of the background information on the following Defendants and BMP-2 concerning other hospitals is to show the egregious methods, which upon information and belief were used at all hospitals.

235. The Defendants allowed and encouraged these practices by Dr. Durrani for the sole purpose of money and greed.

236. David Rattigan was always present in Dr. Durrani's operating rooms as a representative of Medtronic.

237. David Rattigan's sole job was to deliver the BMP-2/Infuse to the Hospitals and make sure that it was inserted correctly into the patient.

238. David Rattigan's presence in the OR further supports the Defendants awareness of Dr. Durrani's fraudulent use of BMP-2/Infuse.

239. **Informed Consent for Surgical or Medical Procedure and Sedation:**

It is the responsibly of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

a. The explanation of the procedure

b. The benefits of the procedure

c. The potential problems that might occur during recuperation

d. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.

e. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.

f. The likelihood of achieving satisfactory results

Completion of the "Consent to Hospital and Medical Treatment" form to examine and treat is NOT sufficient as consent to perform a surgical procedure, invasive procedure, or for medical regimens of substantial risk or that are the subject of human investigation or research.

240. The Defendants had the responsibility to carry out these consent rules.

241. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

242. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

243. Dr. Durrani is a consultant for Medtronic.

244. Defendants did not inform Plaintiffs of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

245. Medtronic, provided in writing to Dr. Durrani the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

246. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

247. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

248. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

249. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

250. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

251. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

252. Dr. Durrani and Children's Hospital personnel did not disclose to Plaintiffs their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

253. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

254. Defendants did not inform Plaintiffs that Dr. Durrani used Infuse/BMP-2 in his surgeries.

255. Plaintiffs would not have allowed BMP-2 to be used by Dr. Durrani in his surgery in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

256. Plaintiffs would not have consented to the use of BMP-2 in Plaintiff's body if informed of the risks by Dr. Durrani or any Children's Hospital personnel.

257. The written informed consent of Dr. Durrani signed by Plaintiffs lacked the disclosure of Infuse/BMP-2's use in his procedures.

258. Plaintiffs never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani or any Children's Hospital personnel.

259. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

260. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

261. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

262. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

263. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

TRIGGERS - RETENTION

264. With respect to Dr. Durrani, West Chester/UC Health did not follow their written medical staff policies and procedures under their professional practice evaluation policy.

265. West Chester/UC Health failed to follow the triggers for peer review from January 2009 through May 2013.

266. The following are the triggers for peer review or other actions as provided by West Chester/UC Health to the Deters Law Office in discovery in related litigation and is a list which by their own admission is not exclusive and is a list they produced after full knowledge of the items Dr. Keith Wilkey, Plaintiffs' experts, considered triggers:

A. Wrong operative procedure performed

B. Serious injury due to medical device

C. Procedure performed on wrong patient

D. Medication resulting in death

E. Delay in diagnosis

F. Autopsy not correlated with clinical diagnosis

G. Delay in treatment resulting in serious injury or death

H. Alleged abuse or neglect

I. Unexpected death

J. Surgical death

K. Mortality review

L. Unplanned second surgeon called to OR

M. MD not credentialed for procedure

N. Focus review

O. Incident reports

P. Contraindication to surgery

Q. Unintended retention of foreign object in a patient after surgery

R. Complications from procedure (i.e. readmits, infections, pneumothorax after procedure)

S. X-ray discrepancies

T. Returns to surgery

U. Transfusion not meeting criteria on order sheet

V. Change in surgery/procedure

W. Laceration/or perforation/puncture of organ during invasive procedure

X. Acute MI or CVA within 48 hours of procedure

Y. Anesthesia complications

Z. MD without timely response to ED or unit call

AA. Risk management issues

BB. Delay in treatment not resulting in serious injury and/or death

CC. Delay in diagnosis not resulting in injury or death

DD. Acute blood loss as indicated by procedure

EE. Appropriate care measures not ordered

FF. Readmission- complication of previous admission

GG. Unplanned admission following surgery

HH. 72 hours returns to ED and readmit same issue

II. Insufficient documentation

JJ. BMP-2

KK. PureGen

LL. Late dictation or no dictation of operative reports or discharge summaries

MM. False claim of spondylolisthesis

NN. False claim of stenosis or its severity

OO. Performing surgeries on patients whose health condition vitiates surgery: age, diabetes, obesity, hypertension, mental health issues, etc.

PP. Shanti Shuffle- Dr. Shanti being forced to do an entire surgery for Dr. Durrani by Dr. Durrani without the patient's knowledge.

QQ. No hospital consents or improper CAST consents

RR. Failed Hardware

SS. Performing surgery not qualified to perform

TT. Dura tear

UU. Having hardware which should be removed, which is never removed

VV. Not using the proper cage with BMP-2

WW. Ignoring radiology results

XX. Misrepresentations to primary care physicians

267. Dr. Keith Wilkey, a board certified spine expert, has reviewed over 213 patient charts at West Chester of Dr. Durrani and signed 213 affidavits of merit as required under CR10 of Ohio Rules of Procedure to file a medical malpractice case and based upon these

reviews over 500 events triggers place which would have required action against Dr. Durrani by West Chester. Defendants intentionally took no action.

268. In 2008, insurance companies became much more selective in what they would authorize for payment. They started only paying for spinal surgeries that were highly indicated, meaning there was rock solid medical evidence to support their necessity for treatment of patients.

269. Certain diagnoses such as spondylolisthesis and severe spinal stenosis have good literature support for complicated lumbar fusion procedures with instrumentation, highly indicated procedures with good outcomes which result in; more pay for Durrani. Dr. Durrani would use these extensively. The data shows Dr. Durrani falsely claimed spondylolisthesis diagnosis 95% of the time.

270. Most of the surgeries Dr. Durrani actually performed were a lesser indication; mainly degenerative disc disease with lesser amounts of spinal stenosis which insurance companies will not usually pay for the more expensive spinal fusion; less pay for Dr. Durrani. This is why Dr. Durrani would claim the conditions of spondylolisthesis.

271. Surgeons have to obtain advanced authorizations from the patient's insurance carrier prior to doing the surgery. If surgeons are requesting to do a surgery with a lesser indication, most of the time it is denied unless the requesting surgeon can convince a "peer surgeon" of the need to do the bigger surgery and demonstrate why this case is an exception to their policies. That takes time and the peer has access to the patient's whole medical record. That peer reviewer could easily have discovered the fraudulent diagnoses Durrani was claiming.

272. Beginning in 2009, Dr. Durrani lied much more often to avoid the whole process and possibility of discovery by the insurance companies.

273. Dr. Durrani didn't do his operative reports on time so as to assist his cover-up of the fraudulent diagnoses.

274. Government has given hospitals incredible power to act as the "watch" for patient's safety and well-being, but with that power comes responsibility.

275. West Chester Hospital had the duty to monitor its physicians via the peer review process and at least on paper, they had the process in place.

276. In that process, West Chester had several "triggers" established which would have resulted in an in-depth peer review. Triggers don't have to be events or behaviors that are malpractice, but are designed to be even more sensitive.

277. Most of those triggers are suggested by the government such as complications and return to surgery. However, hospitals are supposed to adjust their triggers for the individual physicians depending on their practice type and behaviors. This is to insure that the hospital has meaningful triggers for each physician. It wouldn't make sense to monitor operative reports for an internist that doesn't operate. It would make more sense to look at his discharge summaries.

278. For Dr. Durrani, meaningful triggers would have been items tracked during the medical record review of the malpractice claims. Although complications such as hardware failure, nonunion and revision are not mandated by the government for hospital triggers, any responsibility peer review committee should have reviewed Dr. Durrani's results and adjusted the triggers for Dr. Durrani to reflect his higher than normal

complication rate in these areas. Other areas tracked should have included his off-label and contraindicated use of Infusc and PureGen.

279. Defendants failed to act upon an overwhelming amount of material. There were over 591 individual triggers that were ignored by West Chester. That is overwhelming and unforgivable for a hospital to allow, given the power they had to protect their patients from harm.

280. On peer review, they are asked to identify and assist with the removal of known incompetence. A surgeon's duty on the peer review panel is to protect patients from illegal operations. Surgeons look for false and fraudulent diagnoses plus fictitious medical treatment.

281. The peer review committee is asked to sit on the committee for usually two years at a request.

282. West Chester Hospital had bylaws based upon the joint commission accreditation of healthcare organizations known as "The Joint Commission." The principles of the initial credentialing that allowed Dr. Durrani to start operating and mechanisms available to the hospital to stop him from harming other patients a basically equivalent. There are some "minor" variations between state laws but for the most part, they are the same. An example would be the "process" called summary suspension, after it becomes clear of a physician's incompetence, the mechanism to remove him are the same everywhere. Therefore, the situation regarding West Chester and Dr. Durrani are unique only in their depth and degree to which Dr. Durrani's egregious behavior was allowed to harm patients before he was stopped only by the filing of over one hundred lawsuits.

283. The credentialing and peer review work is kept secret from the public.

284. Credentialing is a very lengthy application where 40 to 100 pages of documents are required. Each of these have to be verified by the credentialing personnel from the hospital and then a committee member is assigned to do a further background check into these applicants past work to include calling references, hospitals and training programs.

285. Within some broad limits, one can probe very deep into the past of an applicant because the applicant signs multiple disclosure agreements before the background check. This insures that if needed, the peer review can make good recommendations to the committee chairperson.

286. Given Dr. Durrani's behavior and clinical problems in Cincinnati at the time he was applying for credentials at West Chester, phone calls should have been made regarding Dr. Durrani's past work history, particularly at Children's Hospital. Another "red flag" that Dr. Durrani would have had was the fact he was not board certified by the American Academy of Orthopedic Surgeons or a member of the North American Spine Society.

287. Being board certified and a member of a specialty society is a good way for a hospital to have some external quality check for the applicant. If the applicant doesn't have those in their packet, it's a "red flag" and the reviewer for the committee has to be vigilant and do extra digging.

288. If West Chester and Defendants had called and received reports not favorable to Dr. Durrani the information would be confidential and administration could still take a chance and convince the physicians of the credentialing committee and MEC to allow the privileging anyway. Privileging under these circumstances is usually granted by the staff with very strict terms and the physician would be on a very "short leash."

289. If this happens, the physician is put on a strict probationary period with any violation of the bylaws resulting in termination and databank report is filed.

290. Dr. Durrani was incompetent and he should have had an immediate summary suspension and a National Practitioner's Databank report should have been filed after a fair hearing confirmed the initial suspension. This report would be the only way the public would know that Dr. Durrani was found to be incompetent by his peers at West Chester. This report did not happen and the hospital administration officers, Board members and Defendants were protecting Dr. Durrani from the usual process of peer review.

291. The hospital administration has considerable control of the peer review process. They rightly claim the actual process of reviewing the patient's records and voting on the issue at hand is done by the hospital medical staff. The administration controls all the remaining variables; the physicians assigned to the committee are assigned to review the individual case, which physician is reviewed and the selecting "triggers" for the process and, the "assistants of the committee" that monitor physicians on a daily basis are all hospital employees.

292. According to a review report of Dr. Durrani performed by Dr. Keith Wilkey, 8 of 16 patients OR reports were not done in a thirty day window, it included a lot of fictitious, fraudulent and false diagnoses, two contraindicated use of Infuse used in minors, one cancer after Infuse and several novel surgeries—VATS, AxiaLIF, DLIF. The results of this peer review speak for itself. Had this study been completed, there is no way to conclude otherwise that Dr. Durrani was incompetent. He should have been summarily suspended before the study was done to protect future patients. The peer

review should have reported to the MEC and then Dr. Durrani should have been suspended until a hearing at the MEC level confirmed or denied the summary suspension. A databank report would have been required to be filed by West Chester.

293. West Chester's bylaws clearly state the requirement that OR reports be done within 30 days from the completion of the surgery. Without exceptions, physicians get written notification of their delinquent records and are given anywhere from seven to ten days to correct the deficiency. If the charts are not dictated within that time limit, the physician is summarily suspended and the case is sent to the MEC for their review. This process may be repeated one or two more times, but usually within a six month period, the delinquent physician has their privileges revoked and a databank report filed. Dr. Durrani was given an exception for over four years.

294. Defendants willingly overlooked illegal operations. Dr. Durrani gave false or exaggerated and fraudulent diagnoses plus fictitious medical treatment. His surgical outcomes were horrible.

295. The hospital has to disclose the OR reports and the report included the time and the date of the dictation, to which the delay from the surgery date can be determined. West Chester had to disclose emails between the hospitals and Dr. Durrani. In one email from the CEO, Defendant Joseph to Dr. Durrani, the CEO acknowledges that they knew of Dr. Durrani's dictation violations. Therefore, they had actual knowledge of Dr. Durrani's violations and cannot claim a statutory presumption of immunity from negligent credentialing.

296. The Joint Commission sets the standard and hospital compliance isn't controlled by the state. Hospitals have to have ongoing physician monitoring in place to satisfy the

accreditation requirements. Good hospitals require a medical staff that is willing and able to monitor itself through Practitioner Performance—ongoing professional practice evaluation "OPPE."

297. Since 2009, the Joint Commission has required hospitals, through its medical staff, to conduct an ongoing professional practice evaluation of every privileged practitioner at the hospital, without exception. There are three essentials to OPPE: it must measure certain things (for surgeons, surgical complications and treatment patterns), the measures must be collected and assessed (periodic chart review, observation, discussion with other doctors and nurses), and finally the medical staff must act on its findings (focused professional performance evaluation instituted.) It is a confidential process.

298. Due to the confidentiality, Dr. Durrani's OPPE from the hospital is not available but because West Chester is joint commission accredited and they supposedly meet all their requirements, it is safe to conclude the OPPE process was done two or three times on Dr. Durrani. Once he started at West Chester and then before his re-credentialing every two years. He either resigned, did not reapply, or was revoked around his four year re-credentialing.

299. There is another instance where West Chester administration should have known about the other Dr. Durrani issue in that if the OPPE found problems, the MEC should have required a FPPE, which is an in-depth review with the possible requirement for corrective action, summary suspensions, and recommendation of limitation or termination of privileges. If a FPPE was ongoing and Dr. Durrani resigned during this process, a Databank report should have been filed, which didn't happen.

300. Anytime an event occurs that is significant, called a "trigger" OPPE or an FPPE can be conducted, and given Dr. Durrani's poor performance that should have occurred given a medical staff that was diligent in their duties. The administration had multiple warnings from the medical staff about Dr. Durrani. They knew he was bad and ignored that fact.

INFUSE/BMP-2

301. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

302. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

303. Dr. Durrani is a consultant for Medtronic.

304. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

305. Medtronic, provided in writing to Dr. Durrani and CAST the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

306. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

307. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

308. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4

to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

309. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

310. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

311. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

312. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

313. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

314. Plaintiff was not informed by Defendants that Dr. Durrani used Infuse/BMP-2 in her surgery.

315. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

316. Plaintiff would not have consented to the use of BMP-2 in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

317. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in her procedures.

318. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

319. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

320. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

321. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

322. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

323. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

PUREGEN

324. Dr. Durrani oftentimes used Puregen when performing surgeries.

325. Puregen is a product produced by Alphatec Spine.

326. Dr. Durrani was and is a paid consultant for Alphatec Spine.

327. Dr. Durrani has an ownership stake in the Alphatec Spine.

328. Puregen has never been approved by the FDA for any human use.

329. Puregen is now removed from the market for any use.

330. Dr. Durrani used the product Puregen as bone graft substitute similar to Infuse/BMP-2 during spinal surgeries.

331. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose their intent to use Puregen, nor did they inform Plaintiff that it was a product that was not approved by the FDA for human use.

332. Dr. Durrani used Puregen in Plaintiff in manners not approved by the FDA.

333. Plaintiff was not informed by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel that Dr. Durrani used Puregen in her surgeries.

334. Plaintiff would not have allowed Puregen to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA.

335. Plaintiff would not have consented to the use of Puregen in their body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

336. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Puregen's use in her procedures.

337. Plaintiff never received a verbal disclosure of Puregen from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

338. Defendant Dr. Durrani owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

339. Defendant Dr. Durrani breached his duty by failing to exercise the requisite

degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

340. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: BATTERY

341. Dr. Durrani committed battery against Plaintiff by performing a surgery that was unnecessary, contraindicated for Plaintiff's medical condition, and for which he did not properly obtain informed consent, inter alia, by using BMP-2, PureGen and/or Baxano in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.

342. Plaintiff would not have agreed to the surgeries if they knew the surgeries were unnecessary, not approved by the FDA, and not indicated.

343. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: LACK OF INFORMED CONSENT

344. The informed consent forms from Dr. Durrani and CAST which they required Plaintiff to sign failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani and CAST each required an informed consent release.

345. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before Plaintiff's surgery.

346. Dr. Durrani failed to inform Plaintiff of material risks and dangers inherent or potentially involved with her surgeries and procedures.

347. Had Plaintiff been appropriately informed of the need or lack of need for surgery and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgery or procedures.

348. As a direct and proximate result of the lack of informed consent, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

349. Dr. Durrani's conduct as described above was intentional and reckless.

350. It is outrageous and offends against the generally accepted standards of morality.

351. It was the proximate and actual cause of Plaintiff's psychological injuries, emotional injuries, mental anguish, suffering, and distress.

352. Plaintiff suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

353. Dr. Durrani made material, false representations to Plaintiff and their insurance company related to Plaintiff's treatment including: stating the surgeries were necessary, that Dr. Durrani "could fix" Plaintiff, that more conservative treatment was unnecessary and futile, that the surgery would be simple or was "no big deal", that Plaintiff would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the

surgery was successful, and that Plaintiff was medically stable and ready to be discharged.

354. Dr. Durrani also concealed the potential use of Infuse/BMP-2 and/or Puregen in Plaintiff's surgery, as well as other information, when he had a duty to disclose to Plaintiff his planned use of the same.

355. These misrepresentations and/or concealments were material to Plaintiff because they directly induced Plaintiff to undergo her surgery.

356. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

357. Dr. Durrani made the misrepresentations before, during and after the surgeries with the intent of misleading Plaintiff and their insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgeries, and to induce Plaintiff to undergo the surgeries without regard to medical necessity and only for the purpose of receiving payment.

358. The misrepresentations and/or concealments were made during Plaintiff's office visits at Dr. Durrani's CAST offices.

359. Plaintiff was justified in their reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

360. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo surgeries which were paid for in whole or in part by their insurance company, and suffered all damages as requested in the Prayer for Relief.

COUNT VI: SPOLIATION OF EVIDENCE

361. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

362. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

363. Dr. Durrani's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT VII: LOSS OF CONSORTIUM

364. At all times relevant, the Plaintiffs were married.

365. As a result of the wrongful acts and omissions of Dr. Durrani, Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, loss of affection, loss of assistance, and loss of conjugal fellowship, all to the detriment of Plaintiffs' marital relationship.

366. All the aforesaid injuries and damages were caused proximately by the acts and omissions of Dr. Durrani.

CAST COUNTS:

COUNT I: VICARIOUS LIABILITY

367. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of CAST.

368. Dr. Durrani is in fact, the owner of CAST.

369. Defendant Dr. Durrani was performing within the scope of his employment with CAST during the care and treatment of Plaintiff.

370. Defendant CAST is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.

371. Defendant CAST is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

372. As a direct and proximate result of Defendant CAST's acts and omissions, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: NEGLIGENT HIRING, RETENTION, AND SUPERVISION

373. CAST provided Dr. Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.

374. CAST and Dr. Durrani participated in experiments using BMP-2 and/or Puregen bone graft on patients, including Plaintiff, without obtaining proper informed consent thereby causing harm to Plaintiff.

375. CAST breached its duty to Plaintiff, inter alia, by not supervising or controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiff at CAST.

376. The Safe Medical Device Act required entities such as CAST to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

377. Such disregard for and violations of federal law represents strong evidence that

CAST negligently hired, retained, and supervised Dr. Durrani.

378. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: SPOLIATION OF EVIDENCE

379. CAST, through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

380. CAST, through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

381. CAST's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

382. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

383. CAST's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

384. CAST omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

385. CAST's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and

practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

386. CAST was fully aware of its actions.

387. CAST was fully aware that Plaintiffs were induced by and relied upon CAST's representations at the time CAST was engaged by Plaintiffs.

388. Had Plaintiffs been aware that CAST's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

389. CAST, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

390. CAST's actions were not the result of any bona fide errors.

391. As a result of CAST's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

i. An order requiring that CAST restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

COUNT V: LOSS OF CONSORTIUM

392. At all times relevant, the Plaintiffs were married.

393. As a result of the wrongful acts and omissions of CAST, Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, loss of affection, loss of assistance, and loss of conjugal fellowship, all to the detriment of Plaintiffs' marital relationship.

394. All the aforesaid injuries and damages were caused proximately by the acts and omissions of CAST.

WEST CHESTER HOSPITAL/UC HEALTH COUNTS:

COUNT I: NEGLIGENCE

395. West Chester Hospital/UC Health owed their patient, Plaintiff, through its agents and employees the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

396. West Chester Hospital/UC Health acting through its agents and employees breached their duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, improper assistance during Plaintiff's surgeries and improper follow up care addressing a patient's concerns.

397. The agents and employees who deviated from the standard of care include nurses, physician assistants, residents and other hospital personnel who participated in Plaintiff's surgeries.

398. The management, employees, nurses, technicians, agents and all staff during the scope of their employment and/or agency of West Chester Hospital/UC Health's

knowledge and approval, either knew or should have known the surgery was not medically necessary based upon Dr. Durrani's known practices; the pre-op radiology; the pre-op evaluation and assessment; and the violation of their responsibility under the bylaws, rules, regulations and policies of West Chester Hospital/UC Health.

399. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care by the agents and employees of West Chester Hospital/UC Health, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: NEGLIGENT CREDENTIALING, SUPERVISION, AND RETENTION

400. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiff constitute medical negligence, lack of informed consent, battery, and fraud.

401. West Chester Hospital/UC Health negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician, violating their bylaws and JCAHO rules by:

a. Allowing Dr. Durrani to repeatedly violate the West Chester Hospital/UC Health bylaws with it's full knowledge of the same;

b. Failing to adequately review, look into, and otherwise investigate Dr. Durrani's educational background, work history and peer reviews when he applied for and reapplied for privileges at West Chester Hospital;

c. Ignoring complaints about Dr. Durrani's treatment of patients reported to it by West Chester Hospital staff, doctors, Dr. Durrani's patients and by others;

d. Ignoring information they knew or should have known pertaining to Dr. Durrani's previous privileged time at other Cincinnati area hospitals, including

Children's Hospital, University Hospital, Deaconess Hospital, Good Samaritan Hospital and Christ Hospital.

402. The Safe Medical Device Act required entities such as West Chester Hospital/UC Health to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

403. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: FRAUD

404. West Chester Hospital/UC Health sent out billing to Plaintiff at his home following his surgeries at West Chester Hospital.

405. The exact dates these medical bills were sent out are reflected in those medical bills.

406. These bills constituted affirmative representations by West Chester Hospital/UC Health that the charges related to Plaintiff's surgeries were medically appropriate and properly documented.

407. The bills were sent with the knowledge of West Chester Hospital/UC Health that in fact Plaintiff's surgeries were not appropriately billed and documented and that the services rendered at West Chester Hospital/UC Health associated with Dr. Durrani were not appropriate.

408. The bills sent by West Chester Hospital/UC Health to Plaintiff falsely represented that Plaintiff's surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

409. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for West Chester Hospital/UC Health's services in association with Dr. Durrani's surgeries.

410. As a direct and proximate result of this reliance on the billing of West Chester Hospital/UC Health, Plaintiff incurred medical bills that he otherwise would not have incurred.

411. West Chester Hospital/UC Health also either concealed from Plaintiff facts they knew about Dr. Durrani, including that Infuse/BMP-2 or Puregen would be used in Plaintiff's surgery, or misrepresented to Plaintiff the nature of the surgery, and the particular risks that were involved therein.

412. West Chester Hospital/UC Health's concealments and misrepresentations regarding Infuse/BMP-2 or Puregen and the nature and risks of Plaintiff's surgeries were material facts.

413. West Chester Hospital/ UC Health billed Plaintiff for "INFUS SET BONE GRFT MD" in the amount of $13,214.15 for Plaintiff's December 17, 2010 surgery. "INFUS SET BONE GRFT MD" is Infuse/BMP-2.

414. West Chester Hospital/ UC Health billed, twice, for "ALLOGRAFT PUREGEN MED 1.0 ML" in the total amount of $13,057.20 for Plaintiff's June 13, 2012 surgery.

415. Because of its superior position and professional role as a medical service provider, West Chester Hospital/UC Health had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

416. West Chester Hospital/UC Health intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgery, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at West Chester Hospital/UC Health.

417. Plaintiff was unaware that Infuse/BMP-2 or Puregen would be used in Plaintiff's surgeries and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiff's spine.

418. Had Plaintiff known before Plaintiff's surgeries that Infuse/BMP-2 or Puregen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surgeries with Dr. Durrani at West Chester Hospital/UC Health.

419. As a direct and proximate result of the fraud upon Plaintiff by West Chester Hospital/UC Health, Plaintiff sustained all damages requested in the prayer for relief.

COUNT IV: SPOLIATION OF EVIDENCE

420. West Chester Hospital/UC Health through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

421. West Chester Hospital/UC Health through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

422. West Chester Hospital/UC Health's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT V: OHIO CONSUMER SALES PROTECTION ACT

423. Although the Ohio Consumer Sales Protection Statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

424. West Chester Hospital/UC Health's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

425. West Chester Hospital/UC Health omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

426. West Chester Hospital/UC Health's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

427. West Chester Hospital/UC Health was fully aware of its actions.

428. West Chester Hospital/UC Health was fully aware that Plaintiffs were induced by and relied upon West Chester Hospital/UC Health's representations at the time West Chester Hospital/UC Health was engaged by Plaintiffs.

429. Had Plaintiffs been aware that West Chester Hospital/UC Health's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

430. West Chester Hospital/UC Health, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

431. West Chester Hospital/UC Health 's actions were not the result of any bona fide errors.

432. As a result of West Chester Hospital/UC Health's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

i. An order requiring West Chester Hospital/UC Health restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

COUNT VI: LOSS OF CONSORTIUM

433. At all times relevant, the Plaintiffs were married.

434. As a result of the wrongful acts and omissions of West Chester Hospital/UC Health, Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, loss of affection, loss of assistance, and loss of conjugal fellowship, all to the detriment of Plaintiffs' marital relationship.

435. All the aforesaid injuries and damages were caused proximately by the acts and omissions of West Chester Hospital/UC Health.

436. All the aforesaid injuries and damages were caused proximately by the acts and omissions of West Chester Hospital/UC Health.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests and seeks justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. Past medical bills;
2. Future medical bills;
3. Lost income and benefits;
4. Lost future income and benefits;
5. Loss of ability to earn income;
6. Past pain and suffering;
7. Future pain and suffering;
8. Plaintiff seeks a finding that their injuries are catastrophic under Ohio Rev. Code §2315.18;
9. All incidental costs and expenses incurred as a result of their injuries;
10. The damages to their credit as a result of their injuries;
11. Loss of consortium;
12. Punitive damages;
13. Costs;
14. Attorneys' fees;
15. Interest;
16. All property loss;
17. All other relief to which they are entitled including O.R.C. 1345.01

Based upon 1-17 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiff seeks in excess of $25,000.

Respectfully Submitted,

Matthew Hammer (0092483)
Lindsay L. Boese (0091307)
Attorneys for Plaintiff
5247 Madison Pike
Independence, KY 41051
Phone: 513-729-1999
Fax: 513-381-4084
mhammer@ericdeters.com

JURY DEMAND

Plaintiffs make a demand for a jury under all claims.

Matthew Hammer (0092483)
Lindsay L. Boese (0091307)

UC Health

P.O. Box 740117
Cincinnati, OH 45274-0117

ITEMIZED BILL

04/26/13

Tax ID: 311588499

PATIENT NAME	ACCOUNT #	SEX	AGE	ADMIT DATE	DISCHARGE DATE	
NICHOLS, TERESA WEST CHESTER HOSPITAL	220000767	F	46	12/17/10	12/20/10	4

ATTENDING PHYSICIAN
DURRANI, ABUBAKAR

TERESA NICHOLS
115 KINGS RD

MILFORD OH 45150

CREDIT CARD PAYMENT INFORMATION
CARD NUMBER
SIGNATURE
EXP DATE
SHOW AMOUNT PAID HERE $

8 Return this portion with your payment

DATE OF SERVICE	QUANTITY	SERVICE CODE	ACTIVITY		TRANSACTION AMOUNT
12/17/10	1	272	PROBE NIM BALL TIP 23CM		545.40
12/17/10	1	278	INFUS SET BONE GRFT MD		13,214.15
12/17/10	1	278	FOAM BIOACT VITOSS PACK 5CC		3,051.00
12/17/10	1	270	RC OXYGEN USEAGE / DAY		0.00
12/17/10	2	460	RC OXIMETER SPOTCHECK ADULT	94760	138.00
12/17/10	1	460	RC INCENTIVE SPIR TX	94150	0.00
12/17/10	1	320	DIAG T SPINE 3 VIEWS	72072	390.00
12/17/10	1	320	DIAG FLOURO > 1 HOUR	76001	754.00
12/17/10	1	251	BUPIVACAINE HCL/EPI 0.5-0.0005 VIA		26.85
12/17/10	1	251	BUPIVACAINE HCL/EPI 0.5-0.0005 VIA		26.85
12/17/10	1	251	CALCIUM CHLORIDE 100MG/ML VIAL IV		25.10
12/17/10	1	636	HYDROMORPHONE HCL 2MG/ML DIS SYR I	J1170	28.05
12/17/10	1	636	HYDROMORPHONE HCL 2MG/ML DIS SYR I	J1170	28.05
12/17/10	1	636	METHOCARBAMOL 100MG/ML VIAL INJ	J2800	100.90
12/17/10	1	636	MIDAZOLAM 1MG/ML 2ML VIAL	J2250	25.40
12/17/10	1	636	MORPHINE SULFATE 1MG/ML VIAL INJ	J2270	43.95
12/17/10	1	636	PERPHENAZINE 4MG TAB PO	Q0175	5.65
12/17/10	1	636	RINGERS SOLUTION,LACTATED IVSL IV	J7120	78.25
12/17/10	1	636	RINGERS SOLUTION,LACTATED IVSL IV	J7120	78.25
12/17/10	1	250	SCOPOL HB 1.5MG/72HR PATCH TD		30.15
12/17/10	2	258	SODIUM CHLORIDE 0.9% IRRIGATION 30		100.10
12/17/10	1	250	THROMBIN 5MU VIAL TOP		194.05
12/17/10	2	250	THROMBIN 5MU VIAL TOP		366.80
12/17/10	2	250	THROMBIN 5MU VIAL TOP		366.80
12/17/10	2	251	PROPOFOL 10MG/ML INJECTION (VIAL)		68.25
12/17/10	1	636	MORPHINE SULFATE 2MG/ML DIS SYR IN	J2270	27.60
12/17/10	1	636	MORPHINE SULFATE 2MG/ML DIS SYR IN	J2270	27.60
12/17/10	1	258	SOD. CHLORIDE 0.9% 100ML A/V		79.40
12/17/10	1	258	SOD. CHLORIDE 0.9% 100ML A/V		79.40
12/17/10	1	251	CEFAZOLIN SODIUM 1G VIAL A/V		27.40
12/17/10	1	251	CEFAZOLIN SODIUM 1G VIAL A/V		27.40
12/17/10	1	250	SURGIFLO HEMOSTATIC MATRIX		396.45
12/17/10	2	250	SURGIFLO HEMOSTATIC MATRIX		789.20
12/17/10	1	250	SURGIFLO HEMOSTATIC MATRIX		396.45
12/17/10	1	250	PHARMACY NO-CHARGE ITEM		0.00
12/17/10	1	258	TOTAL IV VOLUME (ML)		0.00
12/17/10	1	272	PERF PLATELET GEL		1,080.00

Need Help?

Questions:
pfs@uchealth.com

Billing Disputes:
UC Health Attn: Billing Disputes
3200 Burnet Ave Cincinnati, OH 45229

Customer Service Hours:
M-TH 8AM - 9PM, F 8AM - 4:30PM
513-585-7600 or 1-800-277-0781

BALANCE DUE

CONTINUED

UC Health

P.O. Box 740117
Cincinnati, OH 45274-0117

ITEMIZED BILL

04/23/13

2 of 6

TAX ID: 311588499

PATIENT NAME	ACCOUNT NUMBER	SEX	AGE	DATE OF SERVICE	DISCHARGE DATE	
NICHOLS, TERESA WEST CHESTER HOSPITAL	220867222	F	46	06/13/12	06/15/12	3

ATTENDING PHYSICIAN
DURRANI, ABUBAKAR

TERESA NICHOLS
115 KINGS RD

MILFORD OH 45150

PAYMENT ENCLOSED
VISA MASTERCARD DISCOVER AMERICAN EXPRESS
CARD NUMBER
SIGNATURE EXP DATE
SHOW AMOUNT PAID HERE $

Return this portion with your payment

DATE OF SERVICE	QUANTITY	SERVICE CODE	ACTIVITY		TRANSACTION AMOUNT
06/13/12	1	272	DIL LG DISP		442.26
06/13/12	2	272	NDL PK 2 TRCR TIP		761.40
06/13/12	1	278	GWIRE SHARP 350MM	C1769	135.00
06/13/12	4	278	GWIRE SEXTANT GUID BLNT	C1769	540.00
06/13/12	1	272	BUR LEGEND MTCH HD 14CMX3MM		197.45
06/13/12	1	272	KNIFE BAYONET LONG 188MM		959.85
06/13/12	1	278	PROFUSE CHIPS 5CC		1,366.20
06/13/12	1	278	PROFUSE CHIPS 5CC		1,366.20
06/13/12	1	278	ALLOGRAFT PUREGEN MED 1.0 ML		6,528.60
06/13/12	1	278	ALLOGRAFT PUREGEN MED 1.0 ML		6,528.60
06/13/12	1	300	CROSSMATCH (IMMEDIATE SPIN)	86920	52.00
06/13/12	1	300	CROSSMATCH (IMMEDIATE SPIN)	86920	52.00
06/13/12	1	300	CROSSMATCH CX (COOMBS)	86922	88.00
06/13/12	1	300	CROSSMATCH CX (COOMBS)	86922	88.00
06/13/12	1	460	RC OXIMETER SPOTCHECK ADULT	94760	86.00
06/13/12	1	460	RC INCENTIVE SPIR TX	94150	0.00
06/13/12	1	320	DIAG LS SPINE 2 OR 3 VIEWS	72100	342.00
06/13/12	1	320	DIAG ABDOMEN, AP VIEW	74000	234.00
06/13/12	1	320	DIAG FLOURO > 1 HOUR	76001	754.00
06/13/12	1	320	FLUORO GUIDE NEEDLE PLACEMENT-BX,A	77002	509.00
06/13/12	2	250	AMITRIPTYLINE HCL 50MG TAB		4.00
06/13/12	1	251	BACITRACIN 50000U VIAL IM		38.85
06/13/12	1	251	BUPIVACAINE HCL 5MG/ML VIAL 30ML		24.85
06/13/12	1	251	BUPIVACAINE HCL/EPI 0.5-0.0005 VIA		26.85
06/13/12	1	636	DIPHENHYDRAMINE HCL 50MG/ML VIAL I	J1200	23.30
06/13/12	1	250	DOCUSATE SODIUM 100MG CAPSULE		1.65
06/13/12	1	251	EPHEDRINE SULFATE 50MG/ML AMP INJ		23.05
06/13/12	2	250	GABAPENTIN 400MG CAP PO		4.25
06/13/12	2	250	GABAPENTIN 400MG CAP PO		4.25
06/13/12	1	636	HYDROMORPHONE HCL 2MG/ML DIS SYR I	J1170	28.05
06/13/12	2	636	METHYLPREDNISOLONE ACET 80MG/ML IN	J1040	71.65
06/13/12	1	636	METHOCARBAMOL 100MG/ML VIAL INJ	J2800	100.90
06/13/12	1	636	METHOCARBAMOL 100MG/ML VIAL INJ	J2800	100.90
06/13/12	1	636	METHOCARBAMOL 100MG/ML VIAL INJ	J2800	100.90
06/13/12	1	636	MIDAZOLAM 1MG/ML 2ML VIAL	J2250	25.40
06/13/12	1	636	MIDAZOLAM 1MG/ML 2ML VIAL	J2250	25.40
06/13/12	1	636	MORPHINE SULFATE 1MG/ML VIAL INJ	J2270	51.70

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pfs@uchealth.com

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513-585-7600 or 1-800-277-0781

CONTINUED

AFFIDAVIT OF MERIT
FOR TERESA NICHOLS

I, Keith Wilkey, MD, after being duly sworn and cautioned state as follows:

1. I have made a preliminary review of all relevant medical records and other information provided to me regarding the above named patient concerning the allegations in her lawsuit filed or to be filed. (I'm fully aware of the lawsuits and claims being filed in what is referred to as the Durrani litigation.)

2. Based upon my preliminary review of the medical records and other information provided to me, my education, training and experience, it is my opinion, based upon a reasonable degree of medical probability that the Defendants, Dr. Durrani, CAST and West Chester Hospital deviated from the standard of care for the care and treatment of the above named patient, including lack of informed consent, and that deviation proximately caused harm and damages to the above named patient.

3. I devote at least one half of my professional time to the active clinical practice in my field of licensure, or its instruction to an accredited school.

4. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.

5. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.

6. The facts support the patient's claim for negligence, battery, lack of consent and fraud.

7. As a result of the negligence and conduct, the patient suffered damages proximately caused by them, including the following:

    A. Permanent disability
    B. Physical deformity and scars
    C. Past, Current and Future Physical and Mental Pain and Suffering
    D. Lost income past, present and future
    E. Loss of enjoyment of life
    F. Past medical expenses
    G. Future medical expenses approximately in the amount of $50,000 to $250,000 depending on course of treatment
    H. Aggravation of a pre-existing condition
    I. Decreased ability to earn income

AFFIANT SAYETH FURTHER NOT

KEITH WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by Keith Wilkey, M.D. on this 7 day of March, 2016.

ANGELA POINSETT
Notary Public - Notary Seal
State of Missouri St Charles County
[illegible] 15133613
[illegible] 18, 2019

Angela Poinsett
NOTARY PUBLIC
My Commission Exp.: 07/18/2019
St Charles County
State of Missouri

ANGELA POINSETT
Notary Public - Notary Seal
State of Missouri, St Charles County
Commission # 15133613
My Commission Expires Jul 18, 2019

COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

TERESA NICHOLS
PLAINTIFF

Use below number on
all future pleadings

-- vs --

No. A 1601569
SUMMONS

ABUBAKAR ATIQ DURRANI M D
DEFENDANT

UC HEALTH
% GH&R BUSINESS SVCS INC D - 4
511 WALNUT ST
CINCINNATI OH 45202

You are notified
that you have been named Defendant(s) in a complaint filed by

TERESA NICHOLS
969 ST RT 28 LOT 77
MILFORD OH 45150

Plaintiff(s)

in the Hamilton County, COMMON PLEAS CIVIL Division,
TRACY WINKLER, 1000 MAIN STREET ROOM 315,
CINCINNATI, OH 45202.
You are hereby summoned and required to serve upon the plaintiff's attorney, or upon the plaintiff, if he/she has no attorney of record, a copy of an answer to the complaint within twenty-eight (28) days after service of this summons on you, exclusive of the day of service. Your answer must be filed with the Court within three (3) days after the service of a copy of the answer on the plaintiff's attorney.

Further, pursuant to Local Rule 10 of Hamilton County, you are also required to file a Notification Form to receive notice of all future hearings.

If you fail to appear and defend, judgement by default will be rendered against you for the relief demanded in the attached complaint.

Name and Address of attorney
MATT HAMMER
5247 MADISON PIKE
INDEPENDENCE KY
41051

TRACY WINKLER
Clerk, Court of Common Pleas
Hamilton County, Ohio

By RICK HOFMANN
Deputy

Date: March 17, 2016

D113856499

COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO

TERESA NICHOLS
PLAINTIFF

Use below number on
all future pleadings

-- vs --

No. A 1601569
SUMMONS

ABUBAKAR ATIQ DURRANI M D
DEFENDANT

WEST CHESTER HOSPITAL LLC
% GH&R BUSINESS SVCS INC D - 3
511 WALNUT ST
CINCINNATI OH 45202

You are notified
that you have been named Defendant(s) in a complaint filed by

TERESA NICHOLS
969 ST RT 28 LOT 77
MILFORD OH 45150

Plaintiff(s)

in the Hamilton County, COMMON PLEAS CIVIL Division,
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Further, pursuant to Local Rule 10 of Hamilton County, you are also required to file a Notification Form to receive notice of all future hearings.

If you fail to appear and defend, judgement by default will be rendered against you for the relief demanded in the attached complaint.

Name and Address of attorney
MATT HAMMER
5247 MADISON PIKE
INDEPENDENCE KY
41051

TRACY WINKLER
Clerk, Court of Common Pleas
Hamilton County, Ohio

By RICK HOFMANN
Deputy

Date: March 17, 2016

D113856489